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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte SEAN CHAMBERS, RAM PAUL, and NORMAN JAFFE

Appeal 2013-008974
Application 12/252,918
Technology Center 3700

Before EDWARD A. BROWN, JILL D. HILL, and LEE L. STEPINA, *Administrative Patent Judges*.

HILL, *Administrative Patent Judge.*

DECISION ON APPEAL

STATEMENT OF THE CASE

Sean Chambers et al. ("Appellants") appeal under 35 U.S.C. § 134(a) from the Examiner's decision to reject claims 1–8, 10–16, 18–21, and 23–25.[1] We have jurisdiction under 35 U.S.C. § 6(b). Oral argument was heard on November 17, 2016.

We AFFIRM.

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[1] Claims 9, 17, and 22 are canceled. Appeal Br. 21, 23, 24 (Claims App.).

CLAIMED SUBJECT MATTER

Independent claims 1 and 18 are pending. Claim 1, reproduced below, illustrates the claimed subject matter, with the disputed limitation italicized.

> 1. A valve device for implantation in a recipient vessel, said valve device comprising:
>
> an expandable support frame; and
>
> a bioprosthetic valve attached to the support frame, the bioprosthetic valve comprising a single leaflet and a contiguous portion of a vessel wall harvested from a multi-leaflet vascular valve, the leaflet defining a free edge and the contiguous portion including the natural margins of attachment between the leaflet and the vessel wall;
>
> the support frame including one or more struts and defining a window portion substantially free of the one or more struts, *the free edge of the leaflet positioned within the window portion such that the entire free edge is able to close against and directly contact a portion of an inner wall of said recipient vessel.*

REJECTION[2]

I. Claims 1–8, 10–16, 18–21, and 23–25 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Kalmann (US 2007/0288086 A1; pub. Dec. 13, 2007) and Dzemeshkevich (US 4,692,164; iss. Sept. 8, 1987). Final Act. 8.

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[2] The rejection of claims 1–8, 10–16, 18–21, and 23–25 under 35 U.S.C. § 103(a) as unpatentable over Stacchino (US 2006/0178740 A1, pub. Aug. 10, 2006) and Dzemeshkevich (US 4,692,164, iss. Sept. 8, 1987) has been withdrawn. Ans. 5.

ANALYSIS

Appellants argue claims 1–8, 10–16, 18–21, and 23–25 as a group. Appeal Br. 14. We select claim 1 as representative. Claims 2–8, 10–16, 18–21, and 23–25 stand or fall with claim 1.

The Examiner finds that Kalmann substantially discloses the limitations of claim 1, including a leaflet having a free edge "positioned within the window portion such that the entire free edge is able to close against and directly contact a portion of the inner wall of said recipient vessel (as seen in Figures 5-23)," but does not disclose a bio-prosthetic valve comprising a contiguous portion of a vessel wall harvested from a multi-leaflet vascular valve. Final Act. 8–9. The Examiner finds, however, that Dzemeshkevich discloses a bio-prosthetic valve 1 comprising "a single leaflet #2 and a contiguous portion of a vessel wall harvested from a multi-leaflet vasculature valve such as an aortic valve (column 3, lines 5-65) or a non-coronary valve (column 6, lines 40-52)." Final Act. 9. The Examiner concludes that it would have been obvious to employ Dzemeshkevich's bio-prosthetic valve in the device of Kalmann to "creat[e] a bio-prosthetic heart valve made from an animal that is thrombo-resistant and causes no hemolysis." *Id.*

Appellants argue that the free edge of Kalmann teaches only the use of synthetic materials, not natural materials, and that Dzemeshkevich cannot cure this deficiency of Kalmann because Dzemeshkevich's "valve leaflet is isolated and protected from the vessel wall [by a spacer [6] and a cover [5] designed to isolate the valve leaflet from the vessel wall, effectively blocking closure of the leaflet free edge against the vessel wall." Appeal Br. 15–16. Appellants refer, *inter alia*, to Dzemeshkevich's disclosure that its

"covering [5] forms a toroidal envelope isolated from inside with a layer of a material impermeable to ingrowth of the biological tissue." *Id.* at 16–17 (citing Dzemeshkevich 5:64–67). According to Appellants, although Dzemeshkevich's valve is biologically derived, one skilled in the art would understand Dzemeshkevich's teaching to require that its cover [5] and spacer [6] are used with its valve leaflet to prevent direct contact of the valve leaflet's free edge with the vessel wall, because the cover and spacer "are principle to the achievement of the object of [Dzemeshkevich's] invention." *Id.* at 17.

To the extent that Appellants contend that the Examiner made an erroneous finding because neither reference teaches both a biologically-derived leaflet and positioning thereof such that the free edge directly contacts the vessel wall (Appeal Br. 16), Appellants are improperly arguing the applied references separately, rather than addressing the Examiner's proposed combination of references. To the extent that Appellants argue that the object of Dzemeshkevich teaches away from the Examiner's proposed combination with Kalmann, we disagree because neither reference criticizes, discredits, or discourages the claimed solution. *See In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004).

In addition, we are not persuaded that the cited portions of Dzemeshkevich render the Examiner's rationale unreasonable. Dzemeshkevich is directed to a bio-prosthetic cardiac valve rather than the single-leaflet venous valve that is claimed and disclosed in Kalmann. Dzemeshkevich discloses that use of bioprosthetic valves (having leaflets preventing blood backflow) was known in the art (Dzemeshkevich 1:38–41, 4:23–29), and discusses the advantages of bioprosthetic valves over

synthetic valves (Dzemeshkevich 2:65–68). While Dzemeshkevich's cardiac valve leaflet is indeed isolated from a vessel wall by a covering that is "impermeable to ingrowth of the biological material" (Dzemeshkevich 5:64–67), Dzemeshkevich's cardiac valve appears to perform a more complex operation than the venous valve claimed by Appellants and disclosed by Kalmann, given its inclusion of cusps 3 and fluid vortices 16 created therein (*see* Dzemeshkevich, Fig. 7, 11:51–12:12), and we are not persuaded that this disclosure would broadly teach one skilled in the art that a bioprosthetic leaflet must be isolated and protected from a vessel wall. Thus, although one skilled in the art would understand that Dzemeshkevich considers natural leaflets to be preferable to synthetic leaflets in its disclosed device, the disclosure of Dzemeshkevich does not support a conclusion that such natural leaflets must or should be isolated from a vessel wall in other devices, such as Kalmann's.

For the reasons set forth above, we sustain the rejection of claim 1. Claims 2–8, 10–16, 18–21, and 23–25 fall with claim 1.

DECISION

We AFFIRM the rejection of claims 1–8, 10–16, 18–21, and 23–25 under 35 U.S.C. § 103(a) as unpatentable over Kalmann and Dzemeshkevich.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a). *See* 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED